February 10, 2023

Vascular Solutions, Inc.
c/o Lisa Gallatin, RAC
Principal Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K102212
Trade/Device Name: D-Stat Dry Silver, D-Stat Dry Clear Silver, D-Stat Dry Wrap Silver, Thrombix Silver
Regulatory Class: Unclassified
Product Code: QSX

Dear Lisa Gallatin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 8, 2011. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSX.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Vascular Solutions, Inc.
% Ms. Lisa Gallatin, RAC
Principal Regulatory Product Specialist
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K102212
Trade/Device Name: D-Stat Dry Clear Silver
D-Stat Dry Silver
D-Stat Dry Wrap Silver
Thrombix Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 24, 2011
Received: March 28, 2011

APR - 8 2011

Dear Ms. Gallatin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102212

Device Name: D-Stat Dry Clear Silver

Indications for Use:

Applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing 4-6 Fr. introducer sheaths. D-Stat Dry Clear Silver contains silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102212

Indications for Use Statement

510(k) Number (if known): K102212

Device Name: D-Stat Dry Silver

Indications for Use:

Applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing 4-6 Fr. introducer sheaths. D-Stat Dry Silver contains silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102212

Indications for Use Statement

510(k) Number (if known): K102212

Device Name: D-Stat Dry Wrap Silver

Indications for Use:

Applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes. D-Stat Dry Wrap Silver contains silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102212

Indications for Use Statement

510(k) Number (if known): K102212

Device Name: Thrombix Silver

Indications for Use:

Applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes. Thrombix Silver contains silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102212

3. 510(k) Summary

[As required by 21 CFR 807.92]

510(k) Number: K102212 **Date prepared:** March 24, 2011

Submitter Information / Contact Person

Manufacturer
Vascular Solutions, Inc. (VSI)
6464 Sycamore Court
Minneapolis, MN 55369 USA
Tel: 763.656.4300; Fax: 763.656.4250
Establishment registration: 2134812

Contact Person
Lisa Gallatin, RAC
Principal Regulatory Product Specialist
Email: lgallatin@vascularsolutions.com
Tel: 763.656.4399; Fax: 763.656.4253

General Information

Trade Name: D-Stat Dry Silver, D-Stat Dry Clear Silver, D-Stat Dry Wrap Silver, Thrombix Silver
Common / Usual Name: Topical Hemostat
Classification Name: Dressing, Wound, Drug
Identification of Equivalent Devices:
K061219 D-Stat Dry (Vascular Solutions, Inc.)
K073264 D-Stat Dry Clear (Vascular Solutions, Inc.)
K083190 D-Stat Dry Wrap (Vascular Solutions, Inc.)
K072117 Thrombix (Vascular Solutions, Inc.)
K041268 Silver Alginate Foam Dressing (ADRI)
K090254 Silver Hydrofiber® Dressing Reinforced with Nylon (ConvaTec, Inc.)

Intended Use

The **D-Stat Dry Silver** and **D-Stat Dry Clear Silver** are applied topically as an adjunct to manual compression and are indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing 4-6 Fr. introducer sheaths. D-Stat Dry Silver and D-Stat Dry Clear Silver contain silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

The **D-Stat Dry Wrap Silver hemostatic bandage** and **Thrombix Silver Hemostasis Patch** are applied topically as an adjunct to manual compression and are indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes. D-Stat Dry Wrap Silver and Thrombix Silver contain silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

Device Description

The D-Stat Dry Silver, D-Stat Dry Clear Silver, D-Stat Dry Wrap Silver and Thrombix Silver products are non-woven gauze pads lyophilized (freeze-dried) with procoagulant (thrombin, calcium chloride and sodium carboxymethylcellulose) and antimicrobial (ionic silver water) components. The D-Stat Dry/Wrap/ Thrombix pad creates a physical barrier to blood flow and facilitates hemostasis by the physiological coagulation-inducing properties of the lyophilized pad combined with compression. The

lyophilized components (including thrombin) facilitate hemostasis through enzymatic cleavage and conversion of fibrinogen to fibrin. These products contain silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad and have not been clinically tested for their ability to reduce local infection, catheter-related bloodstream infections (CRBSI) and skin colonization of microorganisms commonly related to CRBSI .

In the presence of fluids (i.e., blood and wound fluids), ionic silver is released from the silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad. Ionic silver, an atom of silver that is missing one electron, provides the antimicrobial property by altering the protein structure and preventing bacterial cells from carrying out normal functions. The D-Stat Silver products demonstrated an antimicrobial effect in AATCC Test Method 100-2004 and Zone of Inhibition laboratory testing.

An adhesive foam or clear bandage accompanies some products in the family. All products are sterilized by electron-beam irradiation and are intended for single use only.

Summary of Studies

The bench, *in vivo* and *in vitro* testing and results that specifically support the substantial equivalence determination of the subject device to the predicates are tests for thrombin activity, pH, moisture content, wetting time, product conformability, silver content, biocompatibility, hemostatic effectiveness, and antimicrobial activity (AATCC Test Method 100-2004 and Zone of Inhibition). The subject device met all established specifications in the design verification bench testing. Biocompatibility tests satisfying ISO 10993 demonstrated the device was non-cytotoxic, not a significant sensitizer and a negligible irritant, which confirms the D-Stat Silver products are biocompatible. Statistical evaluation of data from an acute topical laceration study in a porcine model showed the time-to-hemostasis for the D-Stat Dry Silver did not exceed the time-to-hemostasis for the D-Stat Dry (no silver). Antimicrobial testing demonstrated that after 24 hours of contact with representative D-Stat Silver test samples, all seven microorganism cultures, including some antibiotic resistant cultures, had greater than a 4 log reduction in microbial population under AATCC Test Method 100-2004 and zone of inhibition testing demonstrated comparable zones between D-Stat Silver and the silver-containing predicate devices.

Statement of Equivalence

The D-Stat Silver products are similar in indications for use and design to currently marketed topical hemostats and wound dressings. Technological differences between the subject and predicate devices were sufficiently addressed through bench, *in vivo* and *in vitro* testing and no new safety or performance issues were raised during biomaterial or design verification testing. As such, the D-Stat Dry Silver products (D-Stat Dry Silver, D-Stat Dry Clear Silver, D-Stat Dry Wrap Silver and Thrombix Silver) can be considered substantially equivalent to the predicate devices.